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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/480,472	06/06/1995	SHERROL H. MCDONOUGH	213/066	9286
21365	7590	12/29/2003	EXAMINER	
GEN PROBE INCORPORATED 10210 GENETIC CENTER DRIVE SAN DIEGO, CA 92121			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/480,472	<b>Applicant(s)</b> MCDONOUGH ET AL.	
	<b>Examiner</b> Ardin Marschel	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See attached listing. is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See attached listing. is/are allowed.
- 6) ☒ Claim(s) See attached listing. is/are rejected.
- 7) ☒ Claim(s) See attached listing. is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed 10/20/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **SUMMARY OF CLAIMS STATUS**

**Pending claims:** 39-42, 48-51, 54-56, 67-73, 75, 78-80, 82-84, 86, 88-90, 92, 93, 95, 96, 98-162, 164-174, 176-213, and 216-231

**Allowed claims:** 42, 55, 56, 75, 78-80, 82, 83, 95, 96, 100-149, 151-157, 164-167, 169-172, 174, 177-179, 185, 187-191, 195, 196, 199-203, 216-221, and 227-231

**Rejected claims:** 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213, and 222-226

**Objected to claims:** 48-51, 54, 93, and 99

**Canceled claims:** 1-38, 43-47, 52, 53, 57-66, 74, 76, 77, 81, 85, 87, 91, 94, 97, 163, 175, 214, and 215

### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213, and 222-226 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddinhaus et al. [J. Clin. Microbiol. (1990) 28 :1751] taken in view of Suzuki et al. [J. of Bact. (1988) 170(6):2886].

This rejection is maintained and reiterated from the previous office action, mailed 6/17/03. Applicants argue that there is no suggestion or motivation to prepare probes and/or primers for distinguishing between nucleic acids of *M. bovis* BCG and *E. coli* or *S. lividans* as described via sequence differences in Suzuki et al. In response the Office action, mailed 8/28/02, originally set forth this rejection and cited the abstract and page 1751 introduction of Boddinhaus et al. as generically suggesting and motivating the preparation of probes and/or primers to distinguish microorganisms via sequence differences therebetween. Thus, such generic suggestion and motivation is reasonably deemed to suggest species of probes and/or primers where the prior art describes sequence differences for preparation of such probes and/or primers. The rejection is then based also on the Suzuki et al. description of a number of sequence differences which therefore in combination with the above pointed to Boddinhaus et al. motivation and suggestion to make probes and/or primers therefrom results in a series of optional probe and/or primer species. This series is deemed to include many such species of

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probes and/or primers some of which are instantly claimed. Applicants have not argued this basis for the rejection nor have they set forth any argument as to what may be unexpected results, for example, regarding the specific instantly claimed species of probes and/or primers. Therefore the instantly claimed probes and/or primers are reasonably suggested and motivated species out of a series of possibilities given the above combination of references.

### **CLAIM OBJECTIONS**

Claims 48-51, 54, 93, and 99 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 22, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER